UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,516	12/08/2003	Robin Edwin Buckingham	P31853C2	2311

7590 05/04/2005

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,516	BUCKINGHAM ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

Detailed Action

The current application is a continuation of 09/939470 now abandoned, which is a continuation of 09/446039 now abandoned, which is the national stage entry of PCT/GB98/02110.

The examiner acknowledges receipt ofthe preliminary amendment of 12/08/2003 cancelling claims 1-22 and adding new claims 23-65. Claims 23-65 will be considered on their merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieveley (US Patent No. 6153632) in view of Pool et al. (US Patent No. 5741803).

Rieveley teaches, in the abstract, a method for the treatment of diabetes mellitus by incorporating one or more oral insulin sensitizers with one or more orally ingested insulin, injected insulin, a sulfonylurea, a biguanide, or an α-glucosidase inhibitor.

Rieveley teaches , in col. 2 line line 30 to col. 3 line 35, that known insulin sensitizers include BRL-49653 (rosglitazone, the compound of the current application), pioglitazone, troglitazone, MC555, ALRT268, LGD1069, chromic picolinate, Diab II, vanadyl sulfate, and chromic polynicotinate; known sulfonylureas include glucotrol (glipizide), diabinase, diabeta (glyburide), micronase , tolinase and orinase; and known biguanides include metformin and glucophage.

Rieveley teaches, in col. 4 lines 40-52, that the insulin sensitizer is to be administered in therapeutic ranges from 1μg to 10g combined or used with one or more

of the orally ingested insulin, injected insulin, a sulfonylurea, a biguanide, or an α-glucosidase inhibitor.

Rieveley teaches, in col. 6 lines 40-61, that the preferred delivery method is by oral administration and that the compounds can be delivered as seperate units at the same or different times and that the compositions can be administered as a single dosage form or in the form of subunits several times a day.

Rievely does not teach a particular dosage or dosage forms of the insulin sensitizers (thiazolidinedione compounds such as rosglitazone), that the insulin sensitizers can be administered as salts or hydrates, or that repaglinide can be used.

The examiner respectfully point out that repaglinide is a known non-sulfonylurea insulin secretagogue that acts in a manner similar to the sulfonylurea insulin secretagogues. It would therefor be obvious to utilize repaglinide in an equivalent manner to the sulfonylurea secretagogues.

Pool et al. teach, in the abstract, a compound of formula I or a tautomeric form thereof and/or a pharmaceutically acceptable solvate thereof for use in treating hyperglycemia. Pool et al. teach, in column 2 lines 5-55, that a preferred compound of formula I is 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]thiazolidine-2,4-dione maleic acid salt (rosiglitazone, a thiazolidinedione compound and the compound presented in the current application). Pool et al. teach in column 5 lines 1-43, that the compounds are particularly suitable for oral administration via unit dosage forms such as tablets and capsules and that the compounds can be administered 1-6 times a day such that the

daily dose for a 70kg human will be in a range from 0.1-6000mg and more preferably 1-1500mg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a thiazolidinedione compound (such as rosglitazone) concurrently with an insulin secretagogue (such as a sulfonylurea or repaglinide) and metformin (a biguanide compound) as the thiazolidinedione class of antidiabetic compounds were known, insulin secretagogues were known and metformin was known and all have been used independently to treat diabetes and Rieveley suggests the combined use of the compounds in the treatment of diabetes.

The examiner respectfully points out the following from MPEP 2144.06: "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill in the art would have been motivated to do so in order to lower the amount of insulin secretagogue (sulfonylurea) or metformin (biguanide) or both needed for treatment of the diabetes patient as indicated and suggested by Rieveley in col. 6 lines 1-60.. One of ordinary skill in the art at the time the invention was made (without evidence to the contrary) would be expected to be able to formulate a dosing regimen of 1-2 times a day with a unit-dosage of 1-12mg per unit dose and

delivered either concurrently or sequentially with an insulin secretagogue and metformin to a patient in need thereof.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER